

Remarks/Arguments

Reconsideration is respectfully requested. Claims 55-69, 73 and 149-150 are pending. Claims 55-69 and 73 are rejected. Claims 149-150 are new.

For the reasons set forth below, Applicants respectfully submit that all pending claims are allowable.

I. Anticipation Rejections

Claims 55-67, 69 and 73 are rejected under 35 U.S.C. §102(b) as being anticipated by B. Aussedat (A user-friendly method for calibrating a subcutaneous glucose sensor-based hypoglycaemic alarm, *Biosensors & Bioelectronics*, Vol. 12, No. 11, pp. 1061-1071, 24 March 1997). See Office Action page 2.

For the reasons set forth below, Applicants respectfully disagree and traverse the Examiner's rejections.

In maintaining the rejections, the Examiner asserts that the ECU with glucose sensor of Aussedat on page 1061 "*appear* to be an integrated receiver that includes, in addition to receiving data stream from a continuous glucose sensor", "a single point glucose monitor (ECU with glucose sensor) which is configured to receive a biological sample to measure glucose concentration in the same, where the measured glucose concentration includes a reference data point". See Office Action Final, p.9. In so asserting, the Examiner correlates the ECU with glucose sensor in Aussedat with the claimed integrated receiver, and further, the Examiner correlates the ECU with glucose sensor of Aussedat with the claimed single point glucose monitor.

As the Examiner is well aware, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also MPEP 2131. Furthermore, it is well established that "[a]ll words in a claim must be considered in judging the

patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). See also MPEP 2143.03.

Aussedat discloses that the glucose sensor was connected through a cable to a wearable ECU using a 6V battery, which controls the sensor applied potential, acquires, filters, stores and displays the sensor current (in nanoamps) or, once the system is calibrated, the estimation of glucose concentration in grams per liter. See Aussedat, page 1063, left column. Then, Aussedat describes that "[o]nce the ECU has recognized two plateaus, the user is asked whether the plateaus are valid. This implies that a blood glucose determination has been successfully performed by another method." See Aussedat, page 1053, right column. Aussedat further discloses that "[t]he plateau recognition software was used to determine when a stable current was achieved..., and a first plasma glucose concentration was determined in blood sampled at the tail vein (Beckman Analyzer, Fullerton, CA). See Aussedat, Page 1063, right column to Page 64, left column.

In other words, contrary to the Examiner's assertions, Aussedat describes blood glucose determination performed by another method (separate from the ECU), and further, refers to a separate device (i.e., separate from the ECU) for the blood glucose determination – using Beckman Analyser. Contrary to the Examiner's assertions, Aussedat does not disclose or suggest the combination set forth in the pending claims including, among others, an integrated receiver that receives the data stream from the continuous glucose sensor, wherein the integrated receiver includes a single point glucose monitor, a processor, and a computer readable memory, wherein the single point glucose monitor is configured to receive a biological sample from the host and to measure the concentration of glucose in the sample, the measured glucose concentration including a reference data point, and wherein the computer readable memory includes instructions configured to cause the processor to process the data stream received from the continuous glucose sensor based on the reference data point, determine a rate of change of the processed data stream received from the continuous

glucose sensor, and calibrate the data stream using glucose concentration measured by the single point glucose monitor based on the rate of change determination as set forth in the pending claims of the present application.

Furthermore, with respect to pending claim 56, the Examiner asserts that Aussedat, in referring to its Figure 1, discloses comparing a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable. Claim 56 is directed to the combination of claim 55 wherein the integrated receiver is configured to reject a reference data point when the rate of change of the data stream is above a threshold. As understood, Aussedat discloses the opposite – that is, its plateau recognition software monitors the sensor output to determine when it has reached a plateau, and when the sensor output shows that the plateau is reached, then the ECU asks for the determination of blood glucose concentration for use in calibration. In other words, contrary to the Examiner's assertions, Aussedat does not compare reference data points (to reject or accept such reference data points). Rather, the plain disclosure of Aussedat shows that the plateau recognition software of ECU that is connected to the glucose sensor through a cable determines when the sensor output has reached a plateau (based on the sensor output, not based on a comparison of the reference data points), and then, when a plateau based on the sensor output is determined, asking or alarming the user for the determination of the blood glucose concentration.

Plateau recognition software

The plateau recognition software triggers an alarm when the sensor output has reached a plateau, asking for the determination of blood glucose concentration, which would be used in the calibration procedure. Two plateaus are detected, one before and one after a glucose load. Parameters

See Aussedat, Page 1063, left column.

In other words, because Aussedat discloses obtaining the blood glucose concentration after the sensor output has reached a plateau, there would not be a

reference data point to reject when a plateau is not detected based on the sensor output.

On the other hand, claim 56 requires, among others, the combination of claim 55 wherein the integrated receiver is configured to reject a reference data point obtained when the rate of change of the data stream is above a threshold.

As understood, Aussedat fails to teach or suggest the combination set forth in pending claim 56. At least for the reasons set forth above and further for the reasons provided in prior responses filed, all of which are renewed herein, Applicants traverse the Examiner's rejections and respectfully submit that Aussedat fails to anticipate the combination set forth in the pending claims. Accordingly, Applicants respectfully submit that all pending claims are allowable.

II. Obviousness Rejections

Claim 68 is rejected under 35 U.S.C. §103(a) as being unpatentable over B. Aussedat (1997). See Office Action page 8.

Applicants herein renew all of the arguments set forth above in distinguishing Aussedat from the claimed combinations, and at least for the same reasons, traverse the Examiner's rejection, and respectfully submit that at least for the same reasons, dependent claim 68 is allowable.

III. New Claims 149-150

Each of new claims 149-150 depend indirectly from independent claim 55. For at least the same reasons as set forth above and renewed herein, Applicants respectfully submit that claims 149-150 are allowable.

No Disclaimers Or Disavowals

Amendments to and/or cancellations of the claims are being made without prejudice and solely to clarify issues before the Examiner and/or to advance prosecution of this application and are not intended as a disavowal of any subject matter and do not constitute an agreement or acquiescence to any objection and/or rejection. Accordingly, by this response Applicants do not concede that previously pending claims are not patentable.

Applicants reserve the right to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any pre-amended and/or cancelled claims, including broader and narrower claims, and including any subject matter found to be disclaimed herein or by any prior prosecution (should such subject matter be found to be disclaimed despite Applicants' statement herein of no such disclaimer). Accordingly, Applicants do not make any disclaimers or disavowals of any subject matter supported by the present disclosure.

Applicants' silence with regard to the Examiner's rejections of and/or objections to certain dependent claims constitutes a recognition by Applicants that the rejections and/or objections are moot based on Applicants' amendment or remarks relative to the independent claim from which the dependent claims depend. Such silence does not constitute an acquiescence to any of the Examiner's objections and/or rejections, and Applicants reserve the right to argue the patentability of such dependent claims at any appropriate time.

Remarks and/or amendments, or a lack of remarks and/or amendments, are not intended to constitute, and should not be construed as, an acquiescence, on the part of Applicants: as to the purported teachings or prior art status of the cited references; as to the characterization of the cited references advanced by the Examiner; or as to any other assertions, allegations or characterizations made by the Examiner at any time in

this case. Applicants reserve the right to challenge the purported teaching and prior art status of the cited references at any appropriate time.

In view of the foregoing, Applicants respectfully submit that all pending claims are allowable, and request the Examiner's early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic or in person discussion would be helpful in advancing the prosecution of the present application, Applicants respectfully request the Examiner to contact Applicants' representative at (510) 652-6418, x82.

Respectfully submitted,
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